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José Marques de Castro

Physiological and Operative Severity Score for the enUmeration of Mortality and morbidity (POSSUM) system for outcome prediction in elderly patients submitted to hip fracture emergency surgery

Sistema Physiological and Operative Severity Score for the enUmeration of Mortality and morbidity (POSSUM) para predição dos resultados clínicos em idosos submetidos a cirurgia urgente por fratura da anca

março, 2017

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Doutor Luís Azevedo

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Doutora Joana Mourão

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FMUP FACULDADE DE MEDICINA UNIVERSIDADE DO PORTO
UNIDADE CURRICULAR
PROJETO DE OPÇÃO
DISSERTAÇÃO / MONOGRAFIA

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Projecto de Opção do 6º ano – DECLARAÇÃO DE REPRODUÇÃO

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DESIGNAÇÃO DA ÁREA DO PROJECTO

Anestesiologia

TÍTULO DISSERTAÇÃO/~~MONOGRAFIA~~ (riscar o que não interessa)

Physiological and Operative Severity Score for the enUmeration of Mortality and morbidity (POSSUM) system for outcome prediction in elderly patients submitted to hip fracture emergency surgery.

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Faculdade de Medicina da Universidade do Porto, 16/03/2017

Assinatura conforme cartão de identificação: José Marques de Castro

Aos meus Pais, à minha Irmã,

Aos meus Avós e restante Família,

Aos meus Amigos

Physiological and Operative Severity Score for the enUmeration of Mortality and morbidity (POSSUM) system for outcome prediction in elderly patients submitted to hip fracture emergency surgery

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Abstract

Background: Older adults have a 5 to 8-fold increased risk for all-cause mortality during the first 3 months after hip fracture, caused by low-energy trauma due to osteoporosis. POSSUM system is used in the assessment of outcomes in surgical patients.

Objective: The aim of this study was to evaluate the performance POSSUM system (POSSUM, P-POSSUM and Orthopedic-POSSUM) on predicting 30-day morbimortality in elderly patients undergoing emergent hip fracture surgery.

Design: Retrospective cohort study.

Setting: From 1st January 2014 to 31st December 2015, at a University Hospital.

Patients: Elderly patients (≥65 years-old) admitted with hip fracture that underwent surgery. From 408 patients selected, 328 were excluded for not being submitted to emergency surgery. Data from the remaining 80 patients was retrospectively collected from the clinical files.

Main outcome measures: POSSUM system's performance and calibration for predicting morbimortality were assessed. Observed vs expected morbidity and mortality were compared using area under the Receiver Operating Characteristic (ROC-AUC) curves and Standardized Mortality Ratio (SMR) and the model goodness of fit was assessed using the Hosmer-Lemeshow test (H-LT).

Results: The overall rate of 30 days mortality and morbidity was 6.3% and 38.8%, respectively. ROC curves of POSSUM system showed good discriminative ability for mortality (AUC=0.879; 95%CI 0.763-0.994) but poor for morbidity (AUC=0.647; 95%CI 0.524-0.771). All models showed good calibration and goodness of fit (H-L T p-values for O-POSSUM/POSSUM and P-POSSUM were respectively 0.4627 and 0.2476 for mortality and 0.0932 for O-POSSUM morbidity). SMR indicated significantly fewer than expected deaths for O-POSSUM/POSSUM (0.525; 95%CI 0.065-0.985) but not for P-POSSUM (1.321; 95%CI 0.163-2.479).

Conclusions: POSSUM system is better for predicting mortality than morbidity. All models showed good calibration and goodness of fit. However, SMRs showed mixed results. We showed that POSSUM can be used for predicting 30-day mortality in elderly patients undergoing emergent hip fracture surgery.

Background

Hip fractures caused by low-energy trauma are one of the most serious consequences of osteoporosis. According to the World Health Organization (WHO), hip fractures frequently result in chronic pain, loss of mobility, decreased functional capacity and increased mortality. They are one of the most serious consequences of osteoporosis; and often caused by low-energy trauma. All patients with this type of fracture often need prolonged hospitalization, with almost all requiring surgical intervention.[(1)] It is estimated that, after a year of hip fracture 20 to 30% of these patients die,[(2)] 50-60% have some kind of functional and/or motor loss and only 30-40% of patients obtain functional recovery levels prior to fracture. The majority still requires long-term assistance care, so their medical and socio-economic impact is meaningful and is not limited to the event itself, but rather its consequences.[(1)]

In Portugal, between year 2000 and 2008, 77 083 hip fractures were recorded[(1)] and studies obtained mortality values of 31% in men and 14.1% in women, after 6 months of hip fracture. In the same study, the overall mortality at 12 months was 26.8%, with values of 48.3% in men and 22.2% in women. In general, mortality rates for this cause increases with age and is more frequent in males, where complications also tend to be more serious.[(2)] All-cause mortality risk in the first 3 months subsequent to hip fracture in older adults increases by 5 to 8-fold. Both women and men face increased annual mortality over time. Excess annual mortality after hip fracture is higher in men than in women at any given age.[(3)]

Copeland et al.[(4)] developed and validated a score system named POSSUM (Physiological and Operative Severity Score for the enUmeration of Mortality and morbidity) featuring 18 factors divided into two component parts 12 physiological factors (PS) and 6 operative factors (OS). Each factor is scored exponentially increasing from 1 to 8 (1, 2, 4 and 8) dependent upon grading. This system has also been subsequently used for comparing surgeons, resource usage and to compare surgical outcomes in different countries.[(5)]

A new risk model (P-POSSUM) was developed and validated in a large single centre cohort in Portsmouth using alternative risk equations for the same variables.[6] However, due to the original authors' lack of confidence in the reporting of perioperative complications this model has no morbidity prediction equation.[6] The POSSUM and P-POSSUM systems have proved to be the most reliable and widely applicable scoring methods, with studies showing its effectiveness in predicting mortality and morbidity rates.[4, 6] Orthopedic-POSSUM (O-POSSUM) system, a minor adjustment of the POSSUM scoring system, demonstrates that POSSUM can be used as an audit aid to assess the quality of orthopaedic care.[7, 8]

The aim of this study is to evaluate the performance POSSUM system score (POSSUM, P-POSSUM and O-POSSUM) on predicting 30-day morbimortality of elderly patients undergoing emergent hip fracture surgery.

Methods

Ethics

This study has received ethical approval from São João Health Centre Medical Ethics Committee, Porto, Portugal on 8th November 2016.

Study design

A retrospective cohort study was conducted in all elderly patients (65 or more years-old) admitted, at a University Hospital (São João's Hospital), with hip fracture, that underwent surgery, from 1st January 2014 to 31st December 2015.

Patients

From 408 patients submitted to hip fracture surgery, 328 were excluded for not being submitted to emergency surgery. Data from the remaining 80 was retrospectively collected from the clinical files and included patient age and gender, diagnosis, type of surgery, date of admission, surgery and discharge of the hospital, ASA, comorbidities, physiological and operative parameters, morbidity and mortality.

POSSUM system

The POSSUM score describes 18 factors in two component parts: 12 physiological factors (PS) and 6 operative factors (OS) (Table 1). Each factor is scored exponentially increasing from 1 to 8 (1, 2, 4 and 8) dependent upon grading.[4, 6, 7] From these values predicted mortality can be calculated using formulae described. P-POSSUM, using alternative risk equations for the same variables, also calculate the predicted mortality.[6] Almost all the score variables were available for every patient, but when a figure was missing, a score of 1 was allocated.

PS and OS were calculated for each admitted patient and entered onto a database and from these values POSSUM, P-POSSUM and O-POSSUM scores were calculated for each patient. Predictions of mortality and morbidity for individual patients were

estimated using the following equations,[4, 6, 7] in which R1 relates to the mortality risk and R2 to the morbidity risk:

Mortality:

POSSUM Ln[R1/(1-R1)]= -7.04 + (0.13 x PS) + (0.16 x OS)

P−POSSUM Ln[R1/(1-R1)]= -9.065 + (0.1692 x PS) + (0.155 x OS)

O-POSSUM Ln [R1/(1-R1)] = -7.04 + (0.13 x PS) + (0.16 x OS)

Morbidity:

O-POSSUM Ln [R2/(1-R2)] = -5.91 + (0.16 x PS) + (0.19 x OS)

These are logistic regression models calculated from PS and OS scores. PS and OS scores are calculated as the sum of the score of each of the items.

The outcome was assessed as 30-day morbidity and mortality, which allowed comparability with the system for general surgery. The hospital mortality and long-term mortality (at 30, 60 and 90 days) was accessed through the consultation of the Electronic Health Record – SClinic and RNU – Registo Nacional de Utentes (National Registers of Patients). The presence of the following complications was recorded as morbidity: infection, hemorrhage, other wound problems, thromboembolic complications, cardiac, respiratory, renal and unanticipated displacement of an implant. Exact definitions have been describe previously.[4] We also recorded other complications as non-fatal cardiac arrest, angina and other cardiac complications, pleural effusion, pneumothorax, bronchospasm, newly required respiratory support, newly required supplemental oxygen and other pulmonary complications, defined by ESA-ESICM joint taskforce on perioperative outcome measures.[9]

Statistical analysis

Descriptive statistics are presented as numbers and percentages for categorical variables; and as mean and standard deviation (SD) for continuous variables, or as

median and inter-quartile range (IQR – 25th percentile – 75th percentile), if the variable empirical distribution function was skewed.

The quality of the POSSUM system score models for mortality and morbidity was assessed. Models goodness-of-fit was assessed by the Hosmer-Lemeshow statistic and test and standardized mortality/morbidity ratios. Discriminative/predictive power of the models was evaluated by ROC curve analysis.

A predictive model like a simple diagnostic test for a particular disease or outcome may classify patients into two groups: those with the outcome as assessed by the test result (test positive) and those without it (test negative). A model or a test are assessed by its ability to diagnose the outcome correctly, whether this is positive or negative.[10] The Receiver Operating Characteristic (ROC) curve is a plot of sensitivity *vs* 1 - specificity and it's one of the most common measures of the global test or model discrimination ability. This curve assesses how well a test or a model discriminates individuals into two classes, such as death and alive comparing the test against the actual outcome. The area under the curve (AUC) of the plot (also known as the C-statistic or C-index) assess the discrimination, with 1 being a perfect discriminating test and 0.5 having no discriminative value.[10-12] Discrimination is acceptable for $0.7 \leq AUC < 0.8$, excellent for $0.8 \leq AUC < 0.9$ and outstanding for $AUC \geq 0.9$.[12] Analysis via ROC curves therefore provides not only a useful means to assess the diagnostic accuracy of a given test or predictive model, but also allows for different diagnostic tests or predictive models to be compared.[10]

To evaluate model performance it is also important to know whether or not the number of observed events matches the number of predicted events over the range of model predictions. An assessment of calibration or goodness-of-fit of a predictive model may, for example, directly compare the observed and predicted probabilities of the event across subgroups. Because “observed risk” or proportions can only be estimated within groups of individuals, measures of calibration usually form subgroups and compare predicted probabilities and observed proportions within these subgroups.[11] The Hosmer-Lemeshow test (H-L T) is the most popular measure of

goodness-of-fit which forms such subgroups, typically using deciles of estimated risk of events. Within each decile of risk, the estimated observed proportion and the average estimated predicted probability are calculated and compared.[11] The estimated mortality and morbidity rates for each individual and group are obtained through the predictions calculated with each one of the model equations (POSSUM, P-POSSUM or O-POSSUM). The H-L T statistic has a chi-squared distribution with g-2 degrees of freedom, where g is the number of subgroups formed. Although deciles of event risk are most commonly used to form subgroups, other categories, such as those formed on the basis of the predicted probabilities themselves (such as 0 to <5%, 5 to <10%, etc.), may in some cases be more clinically useful.[11]

Standardized Mortality Ratio (SMR) is a ratio between the observed number of deaths in a study population and the expected number of deaths, based on the age- and sex-specific rates in a standard population and the age and sex distribution of the study population. If the SMR is significantly greater than 1.0, there is evidence of "excess deaths" in the study population.

The statistical significance level was set at 5% and differences were considered statistical significant when $P<0.05$. Statistical analyses were carried out using SPSS 23.[13]

Results

Over a period of 24 months (from 1st January 2014 to 31st December 2015) there were 408 orthopedic hip operations of which 80 (19.6%) were emergency procedures (36 in 2015 and 44 in 2014). Of these surgeries, 24 (30%) were total hip replacements and 56 (70%) were partial hip replacements. The mean age of individuals studied was 84.1 ± 8.6 SD, with 81% being female. Other baseline demographic and clinical characteristics of the sample are described in Table 2.

The overall rate of 90 days mortality was 13.8% (of which 54.5% occurred during the hospitalization). The overall rate of 30 and 60 days mortality were respectively 6.3% and 7.5%. The overall rate of 30 days morbidity was 38.8%. The detailed list of postoperative complications used to classify the morbidity status is described in Table 3.

The POSSUM system logistic regression equation yields an overall predicted 30 days mortality of 9.41 patients (versus 5 observed) for O-POSSUM/POSSUM and 3.76 patients (versus 5 observed) for P-POSSUM. The O-POSSUM equation predicted 30 days morbidity of 39.16 patients (versus 31 observed) (Tables 4 to 6).

Analysis of area under the Receiver Operating Characteristic (ROC-AUC) curves of POSSUM system showed good discriminative ability for mortality (AUC=0.879; 95%CI 0.763-0.994) but poor for morbidity (AUC=0.647; 95%CI 0.524-0.771) (Figure 1 to 2).

All models showed good calibration as assessed by the ROC curve analysis and adequate goodness of fit as assessed by the Hosmer-Lemeshow test (H-L T) (H-L T p-values for O-POSSUM/POSSUM and P-POSSUM were respectively 0.4627 and 0.2476 for mortality and 0.0932 for O-POSSUM morbidity) (Tables 4 to 6).

Standardized Mortality Ratio (SMR) indicated significantly fewer than expected deaths for O-POSSUM/POSSUM (0.525; 95%CI 0.065-0.985) but not for P-POSSUM (1.321; 95%CI 0.163-2.479). Standardized Morbidity Ratio (SMbR) demonstrated that observed and expected morbidity was similar (0.778; 95%CI 0.504-1.052).

Discussion

While some studies have found evidence that POSSUM adequately predicts individual patient morbidity and mortality risk,[14-16] others have found this score significantly overestimates mortality.[17-19]

P-POSSUM has proven to more accurately predict in-hospital mortality than POSSUM.[6, 14, 18-20] Studies performed in different settings have shown P-POSSUM to both over-predict[17, 21] and under-predict mortality.[14, 22, 23]

A study with patients undergoing major digestive surgery showed poor calibration (goodness of fit) and overestimation of O:E ratios, which considerably limits the value of P-POSSUM for outcomes prediction for particular patients.[24] In others studies, P-POSSUM had the least overestimation making it the most useful predictor of likely postoperative mortality.[25, 26] POSSUM, particularly in lower-risk groups, generally overpredicts mortality[14, 26] and morbidity.[25]

The performance of these models for a variety of surgical specialties, with a systematic review[27] has also been explored, with the P-POSSUM being reported as the most accurate model for predicting postoperative mortality after colorectal cancer surgery and the original POSSUM model as accurate in predicting post-operative complications. However, discrepancy between observed to expected mortality amongst individual studies is large. Similar O:E discrepancies have been reported in other surgical specialties.[26, 28]

This study shows that POSSUM system score models (POSSUM, P-POSSUM and O-POSSUM) have excellent discriminative ability between survivors and non-survivors, which corroborates previous studies,[7, 8] but we couldn't demonstrate the same for morbidity. Regarding model calibration, all models showed good calibration and goodness of fit as assessed by the Hosmer-Lemeshow test (H-L T). Concerning Standardized Mortality Ratios (SMR), only the O-POSSUM/POSSUM indicated significantly fewer than expected deaths.

However, the results and conclusions of the present study ought to be seen in the context of its limitations. First, the retrospective design of our study imposed some limitations, such as missing or incomplete information that is required to calculate some variables. Second, since this study was conducted in a single hospital and only included elderly patients undergoing emergent hip fracture surgery, the sample size is reduced and the number of events is limited. Expanding this study to other centers or performs future prospective studies would improve the findings.

In conclusion, and despite the limitations of the study, we demonstrated that POSSUM system is better for predicting mortality than morbidity; and the POSSUM system can be safely used to predict 30-day mortality in elderly patients undergoing emergent hip fracture surgery, having excellent discriminative ability and good calibration.

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Tables and Figures

Table 1. POSSUM system physiology and operative score variables

Physiology score	***Operative score***
Age	Grade of operation
Cardiac Signs	Number of procedures
Respiratory Signs	Total blood loss
Systolic blood pressure	Peritoneal soiling
Pulse rate	Presence of malignancy
Glasgow Coma Score	Timing of operation
Hemoglobin level	
White blood cell count	
Serum sodium	
Serum potassium	
Serum urea	
Eletrocardiogram	

Table 2. Patient demographics, ASA, Charlson and POSSUM baseline data.

Number of patients	***n=80***
Median age (years) (IQR)	85 (78.25 – 90.75)
Women (%)	65 (81.3)
Men (%)	15 (18.8)
Median ASA (IQR)	3 (2 – 3)
Mean Charlson score (±SD)	2.1 (1.8)
Mean Charlson score age adjusted (±SD)	5.1 (3.3)
Mean hemoglobina (±SD)	12.4 (1.7)
Mean white blood cell count (±SD)	10.7 (3.5)
Mean serum sodium (±SD)	136.6 (4.3)
Mean serum potassium (±SD)	4.1 (0.5)
Mean serum urea (±SD)	56 (28.2)
Abnormal ECG (%)	23.8
Known cardiac co-morbidity (%)	81.3
Known respiratory co-morbidity (%)	3.8
Mean days of post-operative hospitalization (±SD)	12.1 (16.4)

Table 3. The number of patients with postoperative complications.

Complication	***n (%)***
Cardiovascular	
Non-fatal cardiac arrest	0 (0)
Acute myocardial infarction	4 (5)
Congestive heart failure	1 (1.3)
New cardiac arrhythmia	0 (0)
Angina	0 (0)
Stroke	0 (0)
Other cardiac complications	2 (2.5)
Pulmonary	
Pulmonary embolism	1 (1.3)
Respiratory infection	8 (10)
Respiratory failure	9 (11.3)
Pleural effusion	4 (5)
Atelectasis	2 (2.5)
Pneumothorax	1 (1.3)
Bronchospasm	0 (0)
Aspiration pneumonitis	1 (1.3)
New requirement for respiratory support	1 (1.3)
New requirement for supplemental oxygen	6 (7.5)
Other pulmonary complications	0 (0)
Renal	11 (13.8)
Postoperative hemorrhage	8 (10)
Infection	
Surgical site infection (superficial)	4 (5)
Surgical site infection (deep)	2 (2.5)
Surgical site infection (organ/space)	0 (0)
Urinary	8 (10)

Infection source uncertain	2 (2.5)
Other wound problems	2 (2.5)
Unanticipated displacement of an implant	6 (7.5)

Some patients had multiple complications.

Table 4. Hosmer-Lemeshow goodness of fit test for O-POSSUM/POSSUM for 30 days mortality

Groups of risk (deciles)	**Number of observed deaths**	**Number of expected deaths**	**Mean risk of observed mortality**	**Mean risk of expected mortality**	**O:E**	**HL Statistic**
1	2	1.420	0.500	0.355	1.410	0.370
2	1	2.570	0.083	0.214	0.390	1.220
3	0	0.450	0.000	0.149	0.000	0.530
4	2	1.250	0.200	0.125	1.601	0.520
5	0	1.460	0.000	0.098	0.000	1.620
7	0	0.590	0.000	0.084	0.000	0.640
8	0	0.600	0.000	0.074	0.000	0.640
9	0	0.530	0.000	0.066	0.000	0.570
10	0	0.550	0.000	0.055	0.000	0.580

chi-square = 6.68; df = 7; p-value = 0.4627

Table 5. Hosmer-Lemeshow goodness of fit test for P-POSSUM for 30 days mortality

Groups of risk	**Number of observed deaths**	**Number of expected deaths**	**Mean risk of observed mortality**	**Mean risk of expected mortality**	**O:E**	**HL Statistic**
1	2	0.850	0.500	0.212	2.356	1.980
2	1	1.190	0.083	0.099	0.840	0.030
3	0	0.170	0.000	0.057	0.000	0.180
4	2	0.440	0.200	0.044	4.523	5.740
5	0	0.470	0.000	0.031	0.000	0.480
7	0	0.180	0.000	0.025	0.000	0.180
8	0	0.170	0.000	0.021	0.000	0.180
9	0	0.150	0.000	0.018	0.000	0.150
10	0	0.140	0.000	0.014	0.000	0.140

chi-square = 9.07; df = 7; p-value = 0.2476

Table 6. Hosmer-Lemeshow goodness of fit test for O-POSSUM for 30 days morbidity

Groups of risk	**Number of observed**	**Number of expected**	**Mean risk of observed morbidity**	**Mean risk of expected morbidity**	**O:E**	**HL Statistic**
1	3	3.490	0.750	0.872	0.861	0.530
2	6	8.780	0.500	0.732	0.683	3.290
3	0	1.890	0.000	0.629	0.000	5.100
4	6	5.680	0.600	0.568	1.056	0.040
5	6	7.250	0.400	0.483	0.828	0.420
7	2	3.030	0.286	0.433	0.660	0.620
8	4	3.150	0.500	0.394	1.269	0.380
9	1	2.850	0.125	0.357	0.351	1.870
10	3	3.040	0.300	0.304	0.987	0.000

chi-square = 12.23; df = 7; p-value = 0.0932

Figure 1

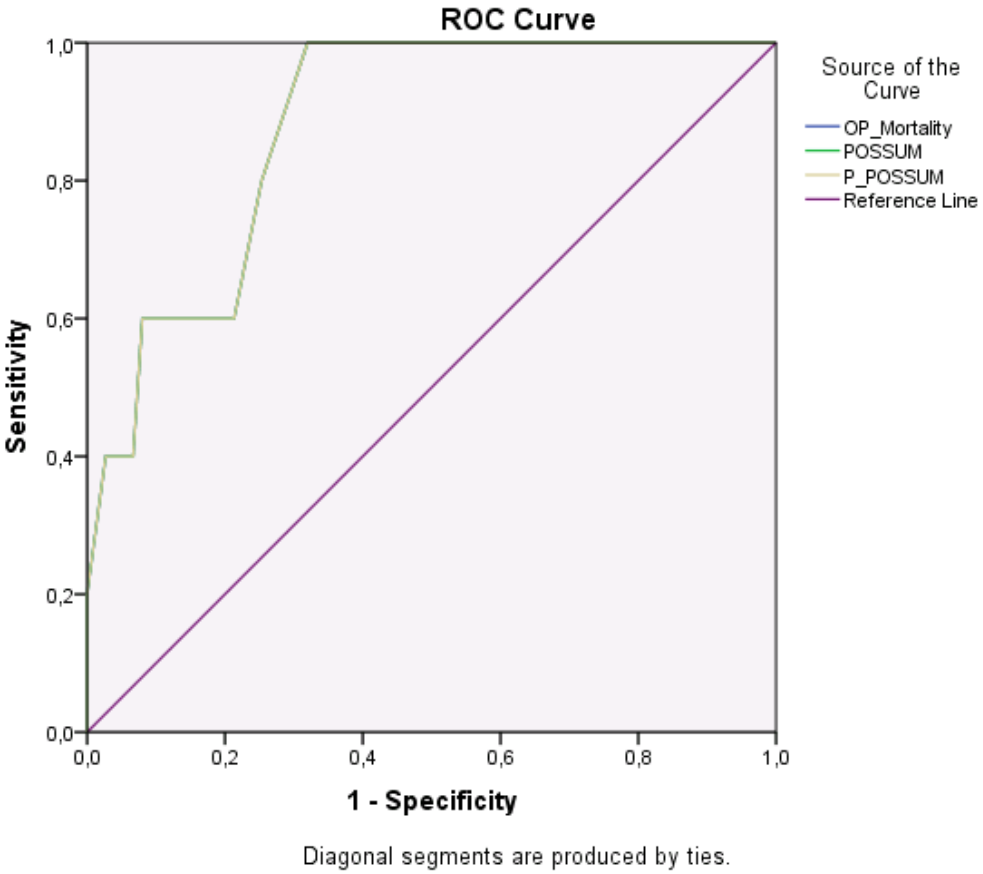
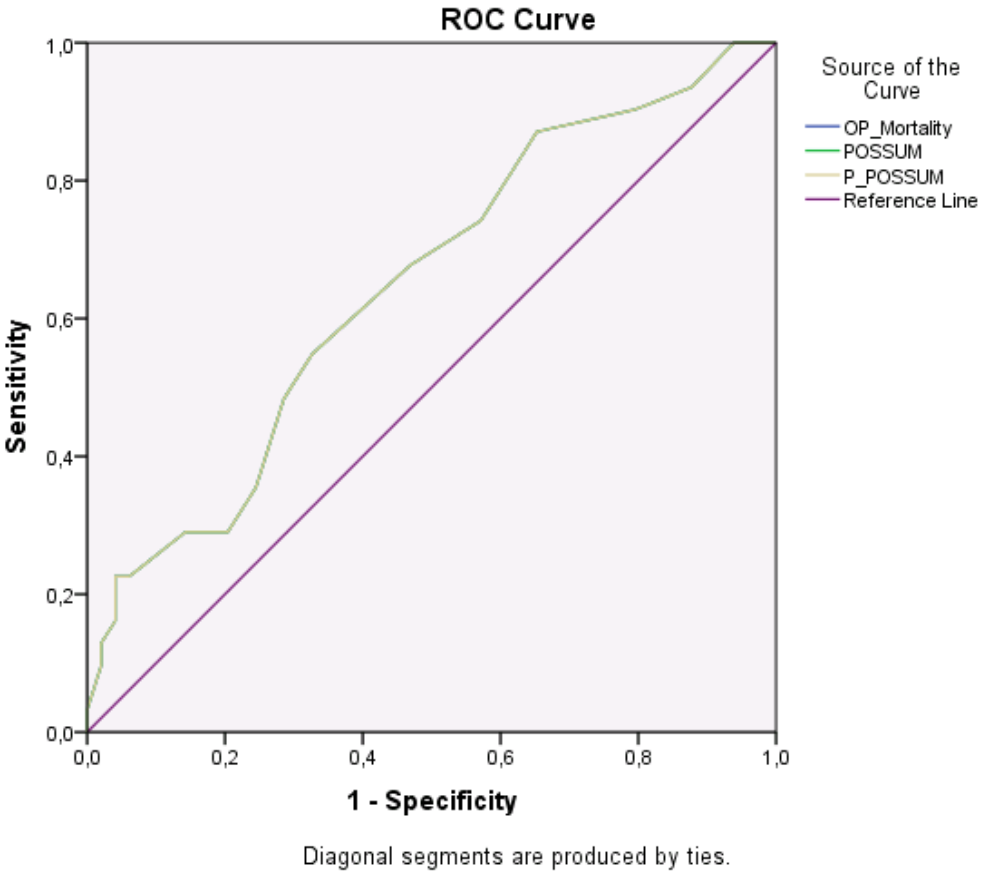

ROC Curve
Sensitivity
1 - Specificity
1,0
0,8
0,6
0,4
0,2
0,0
0,0
0,2
0,4
0,6
0,8
1,0
Source of the Curve
OP_Mortality
POSSUM
P_POSSUM
Reference Line
Diagonal segments are produced by ties.

Figure 2


ROC Curve
Sensitivity
1 - Specificity
1,0
0,8
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0,0
0,2
0,4
0,6
0,8
1,0
Source of the Curve
OP_Mortality
POSSUM
P_POSSUM
Reference Line
Diagonal segments are produced by ties.

Captions

Figure 1. Receiver operating characteristic curve for performance of POSSUM system of 30 days mortality.

Figure 2. Receiver operating characteristic curve for performance of O-POSSUM score of 30 days morbidity.

Agradecimentos

Em primeiro lugar quero agradecer ao Professor Doutor Luís Azevedo, meu orientador, e à Professora Doutora Joana Mourão, minha coorientadora, pelos conselhos e sugestões, confiança, paciência, incentivo e excelente orientação.

À Rita Teles, pelo companheirismo, empenho, assistência, dedicação e incentivo.

À família que eu escolhi – os meus Amigos – que nunca estiveram ausentes e me deram força para ultrapassar os obstáculos que encontrei durante este percurso.

Por último, um agradecimento especial aos meus Pais, que sempre primaram pela minha educação e que me apoiaram continuamente durante todo o meu percurso de vida.

Sozinho este trabalho não seria possível; a todos o meu muito obrigado!

ANEXOS

1. Aprovação da Comissão de Ética para a Saúde e Conselho de Administração do Centro Hospitalar São João

2. Normas editoriais da revista "European Journal of Anaesthesiology"

171-16

DIRECÇÃO CLÍNICA
28/10/2016

Unidade de Investigação

Tomei conhecimento. Nada a opor.

26 Outubro de 2016

A Coordenadora da Unidade de Investigação

(Prof.ª Doutora Ana Azevedo)

AUTORIZADO

CONSELHO DE ADMINISTRAÇÃO REUNIÃO DE 08 NOV 2016

Presidente do Conselho de Administração

(Dr. António Oliveira e Silva)

Diretor Clínico | Enfermeira Diretora | Vogal Executivo | Vogal Executivo

(Prof. Dr. José Artur Paiva) | (Enf.ª Isabel Carrilho) | (Dr. Luís Pinto Correia) | (Dr. Rui Dias Morais)

Exmo. Senhor

Presidente do Conselho de Administração do Centro Hospitalar de S. João – EPE

Aprovado. Ao CA.

(Prof.ª Doutora Ana Azevedo)

Assunto: Pedido de autorização para realização de estudo de investigação

Nome do Investigador Principal: José Marques de Castro

Título do projecto de investigação: Evaluation the performance of Orthopaedic-POSSUM score (O-POSSUM) and Charlson Comorbidity Index on predicting mortality and morbidity of hip fracture urgent surgery in elderly patients.

Pretendendo realizar no Serviço de Anestesiologia do Centro Hospitalar de S. João – EPE o estudo de investigação em epígrafe, solicito a V. Exa., na qualidade de Investigador, autorização para a sua efetivação.

Para o efeito, anexo toda a documentação referida no dossier da Comissão de Ética do Centro Hospitalar de S. João respeitante a projetos de investigação, à qual endereçou pedido de apreciação e parecer.

Com os melhores cumprimentos.

Porto, 31 / 05 / 2016

O INVESTIGADOR

José Marques

(José Marques)

Comissão de Ética para a Saúde – Centro Hospitalar São João / FMUP

Parecer

Título do Projecto: Evaluation the performance of Orthopaedic-POSSUM score (O-POSSUM) and Charlson Comorbidity Índex on predicting mortality and morbidity of hip fracture urgent surgery in elderly patients.

Nome do Investigador Principal: José Marques de Castro

Local onde será realizado o estudo: Serviço de Anestesiologia – CHSJ, havendo autorização da respectiva Diretora de Serviço para a realização do mesmo. Apresenta Declaração de Elo de Ligação – Prof. Doutora Joana Mourão.

Objectivo do estudo:
Avaliar a performance dos scores (O-POSSUM) e Charlson Comorbidity Índex na previsão da mortalidade a 30 e a 60 dias e morbilidade pós-operatória, em idosos submetidos a cirurgia da anca urgente.

Estudo retrospectivo

Período previsto de conclusão: Março 2017

Benefício / Risco: N/A

Respeito pela liberdade e autonomia do sujeito do ensaio: N/A

Confidencialidade dos dados: está garantida a confidencialidade dos dados e esta informação será restrita aos investigadores.

O Investigador Principal dispõe de competência técnica e científica para a realização do estudo.

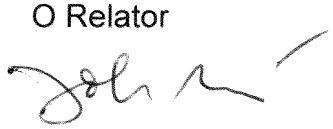
Não prevê a realização de questionário.

Custos: O estudo não prevê custos acrescidos para a instituição.

Parecer: Em face da análise do protocolo de estudo, proponho a sua aprovação pela CES do CHSJ.

Porto, CHSJ, 20 de junho de 2016

O Relator



Dr. John Preto

7. SEGURO

a. *Este estudo/projecto de investigação prevê intervenção clínica que implique a existência de um seguro para os participantes?*

SIM ☐ (Se sim, junte, por favor, cópia da Apólice de Seguro respectiva)
NÃO ☐
NÃO APLICÁVEL ☒

8. TERMO DE RESPONSABILIDADE

Eu, José Marques de Castro, abaixo-assinado, na qualidade de Investigador Principal, declaro por minha honra que as informações prestadas neste questionário são verdadeiras. Mais declaro que, durante o estudo, serão respeitadas as recomendações constantes da Declaração de Helsínquia (com as emendas de Tóquio 1975, Veneza 1983, Hong-Kong 1989, Somerset West 1996 e Edimburgo 2000) e da Organização Mundial da Saúde, no que se refere à experimentação que envolve seres humanos. Aceito, também, a recomendação da CES de que o recrutamento para este estudo se fará junto de doentes que não tenham participado em outro estudo no decurso do actual internamento ou da mesma consulta.

Porto, 31 / 05 / 2016

José Marques
O Investigador Principal

PARECER DA COMISSÃO DE ÉTICA PARA A SAÚDE DO CENTRO HOSPITALAR DE S. JOÃO

emitido na reunião plenária da CES de 23 / Junho / 2016

A Comissão de Ética para a Saúde APROVA por unanimidade o parecer do Relator, pelo que nada tem a opor à realização deste projecto de investigação.

European Journal of Anaesthesiology

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The *European Journal of Anaesthesiology* (EJA) publishes original work of high scientific quality in the field of anaesthesiology, pain, emergency medicine and intensive care. Preference is given to experimental work or clinical observation in man, and to laboratory work of clinical relevance. The journal also publishes commissioned reviews by an authority, editorials, invited commentaries, special articles, pro and con debates, and short reports (correspondences, case reports, short reports of clinical studies).

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The paragraph could read, for example:

Ethical approval for this study (Ethical Committee N° NAC 207) was provided by the Ethical Committee NAC of Geneva University Hospitals, Geneva, Switzerland (Chairperson Prof N. Dupont) on 12 February 2015.

In addition and as stated above, for studies or case reports conducted on human participants you must state clearly in the text that you obtained written informed consent from the study participants; please also look at the latest version of the Declaration of Helsinki. Similarly, for experiments involving animals you must state the care of animal and licensing guidelines under which the study was performed and report these in accordance with the ARRIVE (Animals in Research: Reporting In Vivo Experiments) statement. If ethics clearance was not necessary, or if there was any deviation from these standard ethical requests, please state why it was not required. Please note that the editors may ask you to provide evidence of ethical approval. If you have approval from a National Drug Agency (or similar) please state this and provide details, this can be particularly useful when discussing the use of unlicensed drugs.

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Acceptable registries are:
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www.clinicaltrials.gov
www.ISRCTN.org
www.umin.ac.jp/ctr/index/htm
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- A flow chart showing the progress of participants through the study. The example flowchart may be adapted as required.
- A checklist for editors and reviewers (not for publication) showing that you have described the recommended respective key points in your report.
- The trial registration number and name of the registry. This must be stated at the end of the abstract (see the relevant example in the section 'Structured Abstract').

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These are usually commissioned. Maximum length of reviews is 3500 words. Please provide an unstructured abstract (max. 250 words). Please include a title page giving the author's name, address, email address, phone and fax numbers, as well as an Acknowledgement statement (see paragraph: Acknowledgements) and signed copyright forms.

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1. The clinical problem to be addressed;
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4. The statement on practice itself.

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- Why was this guideline developed?
- How does this statement differ from existing guidelines?
- Why does this statement differ from existing guidelines?

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Background: Explaining the clinical (or other) importance of the study question.

Objective(s): Including a clear statement of the main aim(s) of the study and the major hypothesis tested or research question posed. Avoid statements such as "We aimed to evaluate the effectiveness of X".

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Setting: Include the level of care e.g. primary, secondary; number of participating centres. Be general rather than give the name of the specific centre, but give the geographical location if this is important. Include the dates of the study period.

Patients, other participants (for instance, volunteers) (delete what does not apply): Numbers entering and completing the study, sex, and ethnic group of patients if appropriate. Give clear definitions of how selected, entry and exclusion criteria. For animal studies, this information should be included in the Design or Setting section.

Intervention(s): What, how, when and for how long. This heading can be deleted if there were no interventions but should normally be included for randomised controlled trials, cross over trials, and before and after studies.

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Results: Main results with (for quantitative studies) 95% confidence intervals and, where appropriate, the exact level of statistical significance.

Conclusions: Primary conclusions and their implications, suggest areas for further research if appropriate.

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Assistance with the study: We would like to thank Dr John A. Smith for his assistance with the study.

Financial support and sponsorship: This work was supported by the Department of Anaesthesiology, London Hospital, London, UK.

Conflicts of interest: A has received honoraria from Company Z. B is currently receiving a grant (#12345) from Organisation Y, and C is on the speaker's bureau for Organisation X. For the remaining authors none were declared.

Presentation: Preliminary data for this study were presented as a poster presentation at the European Society of Anaesthesiology (ESA) Euroanaesthesia, 9–12 June 2012, Paris.

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APÊNDICE

1. *Poster* apresentado no Congresso da Sociedade Portuguesa de Anestesiologia 2017

2. Comprovativo de aceitação de *Poster* para o Euroanaesthesia 2017 (Geneva, Switzerland, 3 – 5 June 2017)

Será o sistema Score POSSUM um bom preditor de mortalidade e morbilidade em doentes idosos submetidos a correção cirúrgica de fratura da anca?

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INTRODUÇÃO

O *score* POSSUM é um sistema validado para a previsão da morbilidade e mortalidade aos 30 dias de pós-operatório.[1]

Objetivo: Avaliar o desempenho do sistema POSSUM (POSSUM, P-POSSUM and O-POSSUM) na previsão da morbimortalidade aos 30, 60 e 90 dias em doentes idosos submetidos a correção cirúrgica de fratura da anca.

MÉTODOS

Estudo Retrospetivo Longitudinal

Critérios de Inclusão:

- Doentes idosos (≥ 65 anos)
- Submetidos a correção de fratura da anca em contexto de urgência
- Entre 1 de janeiro 2014 até 31 de dezembro de 2015

Critérios de Exclusão:

- Falta de informação
- Cirurgia não urgente

Score POSSUM: 12 variáveis fisiológicas e 6 scores operativos[2]

- Comorbilidades: Índice de Charlson[3]

  Índice de Charlson ajustado à idade[3]

Análise Estatística:

- Teste Hosmer Lemeshow (HL T)[4]
- Razão Mortalidade/Morbilidade Padronizado (SMR)[5]
- AUC-ROC

RESULTADOS

Nº de doentes	80
Média idade (anos)(variação)	85 (78-91)
Mulheres	65 (81.3%)
Homens	15 (18.8%)
ASA (mediana)(variação)	3 (2-3)
Média Índice de Charlson (±DP)	2.1 (1.8)
Média Índice de Charlson ajustado à idade(±DP)	5.1 (3.3)
Média Hemoglobina (±DP)	12.4 (1.7)g/dL
Média nº Leucócitos (±DP)	10.7 (3.5)x10^9/L
Média Sódio sérico (±DP)	136.6 (4.3)mEq/L
Média Potássio sérico (±DP)	4.1 (0.5)mEq/L
Média Ureia sérica (±DP)	56 (28.2)mg/dL
Anormalidades ECG	23.8%

Tabela 1. Características dos doentes, Classificação ASA e Índice de Charlon

Mortalidade	Nº de doentes
30 dias	5 (6.3%)
60 dias	6 (7.5%)
90 dias	11 (13.8%)

Tabela 2. Mortalidade observada

Morbilidade	Observada	Esperada
Nº doentes	31 (28.75%)	39 (48.75%)

Tabela 3. Morbilidade aos 30 dias.

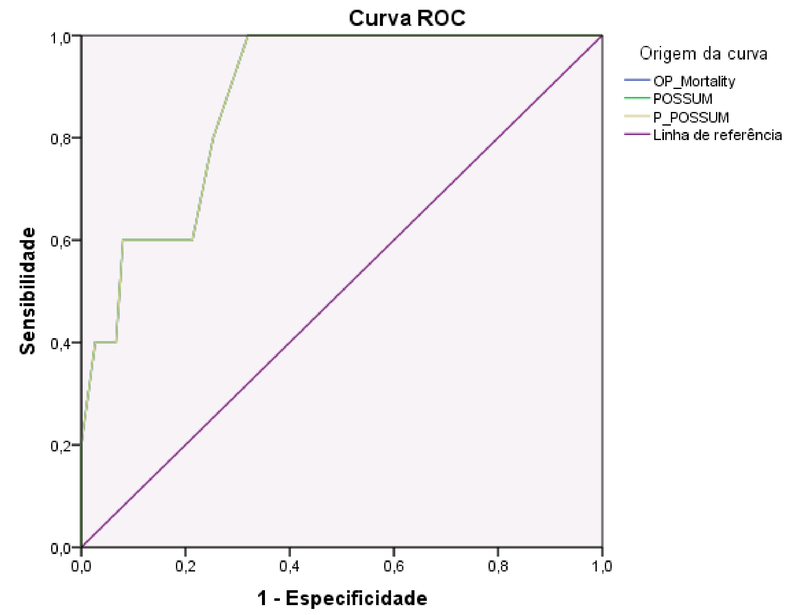

Figura 1. Desempenho do sistema POSSUM na previsão da mortalidade aos 30 dias.

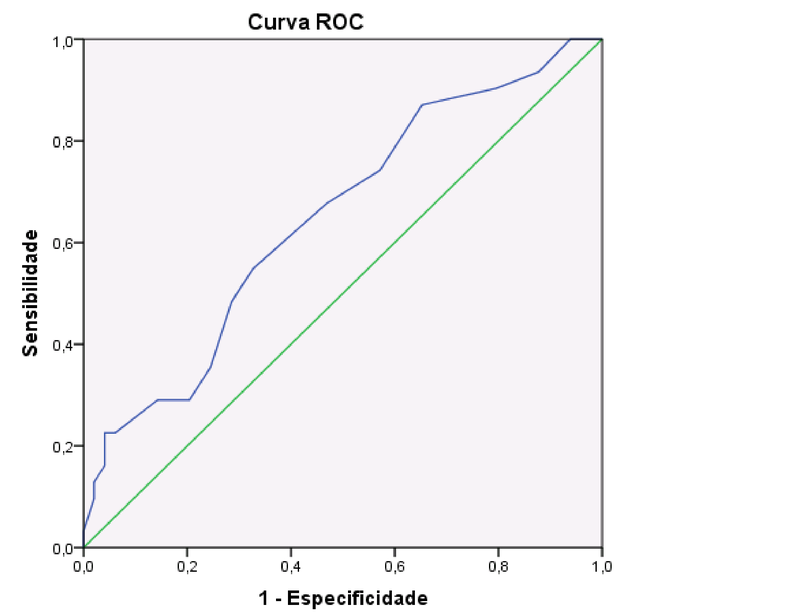

Figura 2. Desempenho do sistema POSSUM na previsão da morbilidade aos 30 dias.

DISCUSSÃO/ CONCLUSÃO

- Todos os modelos apresentaram, boa calibração e qualidade de ajuste.
- O sistema POSSUM (POSSUM, P-POSSUM and O-POSSUM) mostrou excelente capacidade discriminativa relativamente à mortalidade.
- Apenas O-POSSUM sobrevalorizou a mortalidade.
- O modelo POSSUM não obteve um bom desempenho na previsão de morbilidade no nosso grupo de doentes (baixa calibração e discriminação).
- O sistema POSSUM pode ser seguramente usado na previsão da mortaidade aos 30 dias em doentes submetidos a correção cirurgica de fractura da anca, em contexto de urgência.

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Presenter:	**Ana Rita Teles**
Co-Authors:	**Teles A.R.[1], Marques de Castro J.[2], Mourão J.[3], Azevedo L.[4]**
Affiliations:	**[1]Hospital São João, Dept of Anaesthesiology, Porto, Portugal, [2]Faculty of Medicine / University of Oporto, Dept of Anaesthesiology, Porto, Portugal, [3]Hospital São João, Dept of Anesthesia, Dept of Education and Medical Simulation, Dept of Surgery, Faculty of Medicine of University of Porto, Porto, Portugal, [4]Faculty of Medicine, University of Porto, MEDCIDS - Dept of Community Medicine, Information and Health Decision Sciences & CINTESIS - Centre for Health Technology and Services Research, Porto, Portugal**
Abstract Title:	**Physiological and Operative Severity Score for the enUmeration of Mortality and morbidity (POSSUM) system for outcome prediction in elderly patients submitted to hip fracture emergency surgery**
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